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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/940,471	Applicant(s) RISSMANN ET AL.	
	Examiner Kristen L Droesch	Art Unit 3762	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/04 (response, IDS)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *191-217* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *216 and 217* is/are allowed.

6)☒ Claim(s) *191-194,196-200,206,207,209-210 and 215* is/are rejected.

7)☒ Claim(s) *195,201-205,208 and 211-214* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 191-192 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III (5,411,547).

Regarding claim 191, Causey III shows a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system (Col. 1, lines 36-39; Col. 3, lines 28-53).

With respect to claim 192, Causey III shows providing a lead system such that it does not reside in the patient's vasculature (Fig. 4).

3. Claims 191- 194, 196-200, 207, 210, and 215 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahl et al. (5,230,337).

Regarding claims 191, Dahl et al. shows a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without

contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system (Col. 9, line 52- Col. 10, lines 6).

With respect to claim 192, Dahl et al. shows providing a lead system such that it does not reside in the patient's vasculature (Fig. 22).

Regarding claims 193-194, Dahl et al. shows sensing an abnormality in a patient's sinus rhythm making use of only electrodes (188, 190) disposed outside the patient's heart and vasculature (Col. 9, line 52- Col. 10, lines 6; Fig. 22).

With respect to claims 196-197, Dahl et al. shows determining if the patient has an abnormally fast heartbeat or determining if the patient is likely experiencing defibrillation (Col. 1, lines 20-30).

Regarding claim 198, Dahl et al. shows the electrodes (188, 190) are part of the lead system (Fig .22).

With respect to claim 199, Dahl et al. shows at least one of the electrodes (188, 190) in the lead system is also an electrode used for discharging energy (Col. 9, line 52- Col. 10, lines 6; Fig. 22).

Regarding claims 200, and 210, Dahl et al. shows implanting the device between approximately the third rib and the twelfth rib of the patient (Fig. 22).

With respect to claim 207, Dahl et al. shows a method comprising providing a lead assembly including a first electrode (188, 190) implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery,

and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair (188, 190) (Col. 1, lines 20-30; Col. 9, line 52- Col. 10, lines 6; Fig. 22).

Regarding claim 215, Dahl et al. shows providing a lead assembly outside of the patient's vasculature (Fig. 22).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 200 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bardy (5,292,338). Causey III is as explained before. Causey fails to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy, which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to

one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 206 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 205. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

8. Claim 195, 201-205, 208, 211-214 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 216-217 are allowed.

Regarding claim 195, the prior art of record fails to teach or suggest a method comprising implanting a device having a power source and energy storage system into a patient; providing a

lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; sensing an abnormality in the patient's sinus rhythm using electrodes disposed internally to the patient but not contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system in combination with sensing an abnormality includes determining whether the patient has an abnormally slow heartbeat.

With respect to claim 201-202, the prior art of record fails to teach or suggest a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system in combination with implanting the device at about the left axillary line.

Regarding claim 203, the prior art of record fails to teach or suggest a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in

the lead system in combination with providing an implantable device including implanting the stimulus device approximately level with the cardiac apex.

With respect to claim 204, the prior art of record fails to teach or suggest a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system in combination with implanting the device at a subcutaneous location along the inframammary crease of the patient.

Regarding claim 205, the prior art of record fails to teach or suggest a method comprising implanting a device having a power source and energy storage system into a patient; providing a lead system having one or more electrodes for the device, the lead system is disposed internally to the patient without contacting the patient's heart; coupling the power source to the energy storage system (capacitor); storing energy in the energy storage system; and discharging energy from the energy storage system to the patient including using at least one electrode disposed in the lead system in combination with the step of discharging the energy using a first electrode that is part of the lead system and a second electrode disposed on the device itself.

With respect to claim 208, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second

electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair including the second electrode which is provided on a housing housing.

Regarding claim 209, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair including the second electrode in combination with the lead assembly including a third electrode disposed such that it does not touch the heart and the sensing electrode pair includes the first and second electrodes and the stimulus pair includes the second and third electrodes.

With respect to claim 211-212, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's

heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair including the second electrode in combination with implanting the device at about the left axillary line.

Regarding claim 213, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair including the second electrode in combination with providing an implantable device including implanting the stimulus device approximately level with the cardiac apex.

With respect to claim 214, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair

including the second electrode in combination with implanting the device at a subcutaneous location along the inframammary crease of the patient.

With respect to claims 216-217, the prior art of record fails to teach or suggest a method comprising providing a lead assembly including a first electrode implanted in a patient outside the patient's vasculature; providing a device including a battery, means for storing energy, and a housing with a second electrode coupled thereon and coupled to the lead assembly and placed approximately between the third and twelfth ribs at approximately the left axillary line along the inframammary crease; sensing far-field signals using a sensing electrode pair; determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair including the second electrode.

Response to Arguments

10. Applicant's arguments with respect to claims 191-194, 196-200, 206-207, 210, and 215 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Droesch

kld

Patricia Bianco
Primary Examiner
3/22/04